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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/501,714	02/10/00	AU-YOUNG	J PF-0309-3 DI
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LEGAL DEPARTMENT
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HM22/0521

EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

12

DATE MAILED:

05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/501,714

Applicant(s)
Au-Young et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Mar 12, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 43-52, 54-61, and 65-68 is/are pending in the application.

Of the above, claim(s) 43, 44, 50, 51, and 57-61 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 45, 47-49, 52, 54-56, and 66-68 is/are rejected.

☒ Claim(s) 46 and 65 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The amendment filed March 12, 2001 canceling claim 53 and amending claim 49 has been entered.

Claims 43-52, 54-61 and 65-68 are pending.

Claims 45-49, 52, 54-56 and 65-68 are under consideration, claims 43, 44, 50, 51 and 57-61 are withdrawn.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 45, with dependent claims 47-49 and claim 52, with dependent claims 54-56 and 66-68, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules with either SEQ ID NOS: 2 or 4; or DNA having the limitations of encoding a protein having the SEQ ID NOs: 1 or 3; or any DNA

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which is 90% identical to SEQ ID NOs:2 or 4; or encodes a protein that is 90% identical to SEQ ID NOs:1 or 3.

This rejection is reiterated from the Office action mailed December 4, 2000.

In their Remarks filed March 12, 2001 Applicants argue that "polypeptide variants having at least 90% identity to SEQ ID NO:1 and SEQ ID NO:3 are described, for example, at page 16, lines 20-23" (page 7, penultimate paragraph). The careful reading of these lines revealed no structure of any representative of said variants.

Claims 54-56 and 66 are further drawn to a method of use of a probe comprising at least 16, 20, 30 or 60 contiguous nucleotides of said sequences. This genus includes many structurally and functionally unrelated DNAs.

The specification does not disclose structural, physico-chemical or biological characteristics of a DNA comprising at least 16, 20, 30 or 60 contiguous nucleotides. The specification does not teach correlation between the structure and the function of the genus. Therefore, based on the instant disclosure, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of a DNA encoding a polypeptide comprising a fragment of SEQ ID NO:1 or SEQ ID NO:3 or a DNA encoding a polypeptide comprising a sequence having 90% identity to SEQ ID NO:1 or SEQ ID

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NO:3 and a fragment thereof. Thus, a DNA encoding a polypeptide comprising a sequence having 90% identity to SEQ ID NO:1 or SEQ ID NO:3 and a fragment thereof and a DNA encoding a polypeptide comprising a fragment of SEQ ID NO:1 or SEQ ID NO:3 lack sufficient written description needed to practice the invention of claims 45, 47-49, 52, 54-56, 66-68.

Claims 54-56 and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of use of a DNA of SEQ ID NO:2 or SEQ ID NO:4, does not reasonably provide enablement for a method of use of a DNA comprising a fragment thereof or a fragment of a 90% identical sequence encoding a polypeptide having no known function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 54-56 and 66 are drawn to a method of use of a DNA comprising at least 16, 20, 30 or 60 contiguous nucleotides of SEQ ID NO:2 or SEQ ID NO:4 or 90% identical sequences.

This rejection is reiterated from the Office action mailed December 4, 2000.

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In their Remarks filed March 12, 2001 Applicants argue that "issues [how to modify the structure without effecting the activity] are simply not relevant to naturally-occurring polypeptides" (page 15, 1st paragraph). The examiner notes that the rejection is made of a DNA **comprising** 16-60 nucleotides of SEQ ID NO: 2 or SEQ ID NO:4, wherein the structure of the entire sequence is unknown and the function of an encoded polypeptide, if any, is unknown.

Claim Rejections - 35 USC § 102

Claims 45 and 52 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al.(accession N93316).

Hillier et al. (accession N93316) teach an EST of 482 bp that has 99.2% identity to nucleotides 817-1298 of SEQ ID NO:2.

Claims 45 and 52 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al.(accession W63690).

Hillier et al (accession W63690) teach an EST of 661 bp that has 93.6% identity to nucleotides 23-618 of SEQ ID NO:4.

Claims 45 and 52 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al.(accession AA020916).

Hillier et al (accession AA020916) teach an EST of 646 bp that has 94.6% identity to nucleotides 26-638 of SEQ ID NO:4.

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Claims 45 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Weissenbach et al.

Weissenbach et al (accession Z52396) teach a 332 bp DNA fragment that is 95% identical to nucleotides 1093-1211 of SEQ ID NO:2.

The above sequences comprise at least 60 contiguous nucleotides of SEQ ID NO:2 or SEQ ID NO:4 as required by claim 53. Claim 52 is included in this rejection because a naturally-occurring sequence is not limited to 90% sequence identity to the full-length SEQ ID NO:2 or SEQ ID NO:4. Claim 45 is rejected because the above DNA encode a biologically active fragment of SEQ ID NO:2 or SEQ ID NO:4.

This rejection is reiterated from the Office action mailed December 4, 2000.

In their Remarks filed March 12, 2001 Applicants argue that 90% identity to the sequence "means that one must make a comparison across the full length of SEQ ID NO:1 or SEQ ID NO:3" (page 16, penultimate paragraph). This not universally accepted in the art and is not recited in the claims.

Claim Rejections - 35 USC § 103

Claims 54 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Hillier et al. (accession N933160, accession W63690, accession AA020916) or Weissenbach et al. (accession Z52396).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the EST discussed above in hybridization assays with or without the amplification step and for screening of test compounds. The motivation and expectations of success are provided by the state of the art in which hybridization assays and screening of libraries is an intended use of ESTs.

This rejection is reiterated from the Office action mailed December 4, 2000.

Applicants do not argue this rejection.

Double Patenting

Claims 45-49 and 52 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 5,922,567 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Claims 45-49 and 52 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 6,001,598 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

This rejection is reiterated from the Office action mailed December 4, 2000. Applicants consideration for filing a TD stated in Remarks filed March 12, 2001 is noted. The rejection is maintained until a TD is filed.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner